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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
704

Refer to: CFN 1124318

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

December 3, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Jerri Pierce, Administrator
Yater Medical Group
1780 Massachusetts Avenue
Washington, DC 20036

Inspection ID# T00056T66

Dear Ms. Pierce:

Your facility was inspected on October 10, 17 and 23, 1997, by a representative from the Food and Drug Administration (FDA) and the District of Columbia's Radiological Health Program. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards), as specified in Title 21, Code of Federal Regulations, Part 900.12, as follows:

> **Technologist [redacted] did not meet the requirement of being licensed by a State or board certified by any of the approved boards, and was allowed to perform mammography independently.** Corrective actions should be put into place to allow your facility to prevent unqualified personnel from practicing mammography. Not only was [redacted] not qualified to practice mammography, but your facility failed to have documentation on hand proving the qualifications of your radiologists and physicists.

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility. Also, the following Level 2 findings either have not been addressed or have been addressed inadequately by your facility:

> **The number of speck groups scored in the phantom image was 2.0 and did not meet the required number.** In your response, please submit a copy of the invoice left by your processor service personnel and two phantom image films shot using the technique for an average 4.2 cm 50% adipose, 50% glandular tissue breast.

No medical audit system to track positive mammograms was in place. [redacted] was contacted and it was determined they were not tracking positive mammograms from your facility. According to [redacted] it is the individual facility's responsibility to do their own tracking.

Doctors [redacted] and [redacted] did not meet the initial training requirement of 40 hours of continuing medical education in mammography. There is no evidence that [redacted] received 40 hours of training in mammography. If they did receive such training prior to October 1, 1994, they can attest to the training. If the training was received after October 1, 1994, they must submit documentation (e.g., certificates or letters) of the training.

Doctor [redacted] did not meet the requirement of having read and interpreted mammograms from the examinations of at least 240 patients in 6 months. There is no evidence that [redacted] met this requirement. If she did read the required mammograms prior to October 1, 1994, she can attest to meeting the requirement. If the films were read after October 1, 1994, she must submit a letter from the radiologist who directly supervised the reading or from the residency program in which she participated.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identified, and promptly initiating permanent corrective actions.

If you fail to promptly correct the deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- Impose civil money penalties on a facility up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards;
- Suspend or revoke a facility's FDA certificate for failure to comply with the Standards;
- Seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action, therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- The specific steps you have taken to correct all of the violations noted in this letter;
- Each step your facility is taking to prevent the recurrence of similar violations;
- Equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- Sample records that demonstrate proper record keeping procedures, if the noncompliances that were found relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to the Food and Drug Administration, Richmond Resident Post, Suite 424, 10710 Midlothian Turnpike, Richmond, Virginia 23235, Attn: Scott J. MacIntire, Compliance Officer. Also, send a copy to the State radiation control office that conducted the inspection referenced in this letter. You may choose to address both FDA and State requirements in your response.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Elizabeth Laudig at (410) 962-3591, extension 159.

Sincerely yours,

Elaine Knowles Cole
Baltimore District Director

cc: Pharmaceutical, Radiological and
Medical Devices Control Division
Department of Consumer and Regulatory Affairs
614 H Street, NW, Room 1116
Washington, DC 20001